



INTELLIGENT TUTORING SYSTEM: UTILIZING USER PROFILING IN REGULATORY AFFAIRS COURSES

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ABSTRACT

Introduction: In higher education, institutions, and faculty members confront mounting pressures to deliver quality teaching and learning experiences while contending with limited resources. A pivotal challenge in this situation is the academic preparedness of students, often cited as a primary contributor to low academic performance. To address this challenge, tutorials are evolving to meet the diverse needs of students, particularly those entering higher education with varying levels of academic readiness.

User profiling, an innovative tool within ITS, collects and analyses learner characteristics to tailor learning content, strategies, and interactions. In the specialized domain of regulatory affairs, where a comprehensive understanding of various domains is essential, integrating an ITS with user profiling capabilities offers a promising avenue to enhance the learning experience. This study aims to develop and evaluate an ITS-based tutorial specifically designed for postgraduate students specializing in regulatory affairs.

Methodology: This study involved creating distinct modules tailored for the architecture of an ITS, with a focus on the drug product life cycle. Utilizing an Initial Teaching System (ITS) tool, a conceptual map assessed students' prior knowledge, facilitating the identification of slow and fast learners. A supplementary tutorial, comprising student and expert knowledge modules, was developed based on student feedback. After an 8-week tutorial phase, student feedback was gathered via questionnaires and interviews, revealing insights into the acceptance and usability of the ITS among PG Regulatory Affairs students.

Result and conclusion: The focus group interviews revealed that the ITS offers flexibility for learning anytime, anywhere, enables material review, and fosters an effective learning environment.

KEYWORDS: Intelligent Tutoring System, User Profile In Its, Artificial Intelligence, Adaptive Learning Platform, Its In Regulatory Course

1. INTRODUCTION

Higher education institutions (HEIs) and their faculty members are facing increasing pressures to deliver effective teaching and learning experiences within existing resource constraints. A significant challenge in this context is the academic preparedness of students, a factor often cited as the primary contributor to poor academic performance. The consequences of inadequate preparation from earlier education stages greatly burden HEIs (1).

Addressing this challenge, the role of tutorials is evolving to meet the diverse needs of students, especially those entering higher education with varying levels of academic readiness. Tutorials have become instrumental in bridging gaps in academic preparation, providing personalized assistance, and cultivating interactive and participatory learning environments (2).

Traditional teaching methods have undergone a change in the modern educational landscape with the integration of technology and data-driven approaches. ITS stands for Intelligent Tutoring Systems, a category of computer-based learning environments created to replicate the advantages

of human tutoring one-on-one. By using technologies such as artificial intelligence, machine learning, and data analytics, ITS has become more widely recognized for its ability to provide customized possibilities for learning (1). Particularly in highly specialized fields like regulatory affairs, user profiling has shown to be an invaluable tool for improving the effectiveness of courses. An intelligent tutoring system utilizes artificial intelligence techniques to adapt to learners' needs and preferences, with user profiling collecting and analyzing information about learners' characteristics such as knowledge, skills, goals, preferences, and personality. This information helps tailor learning content, strategy, and interaction to the learner's profile, providing more relevant and effective feedback and guidance (3) Regulatory affairs courses focus on ensuring compliance with laws governing the development, testing, manufacturing, and marketing of pharmaceutical, biotechnology, and medical device products. The regulatory affairs course typically requires a foundational understanding of various domains such as formulation, manufacturing, quality control, clinical trials, clinical investigation, marketing strategies, risk assessment, pharmacovigilance, and quality assurance principles. This comprehensive knowledge base is essential for navigating the regulatory landscape effectively.

However, understanding the foundation level of prerequisite knowledge among students entering the regulatory affairs course can be challenging, given the diverse domains it encompasses, and assessing the baseline understanding of students in these areas can be complex (4).

An ITS employing user profiling in regulatory affairs courses offers a personalized and engaging learning experience. For instance, it can assess students' prior knowledge and learning goals, offering customized learning paths and materials aligned with individual levels and objectives.

Furthermore, an ITS with user profiling capabilities can deliver timely and appropriate feedback and hints to help students overcome challenges and achieve mastery. A sample tutorial for postgraduate entrants to the regulatory affairs specialization was prepared and utilized, with results analyzed to assess the effectiveness of this innovative approach (5).

Developing an ITS-based user profiling technique tailored for students enrolled in Regulatory Affairs courses holds significant potential. Such a technique could prove invaluable in enhancing the learning experience and addressing the specific needs of students in this field. The project focused on developing a tutorial based on ITS (Intelligent Tutoring System) designed specifically for postgraduate students specializing in regulatory affairs. The tutorial was evaluated for its effectiveness and outcomes using questionnaire.

2. METHODOLOGY

In this phase, the development of the Intelligent Tutoring System involved the preparation of its architecture. This crucial step lays the foundation for creating an effective and adaptive learning environment.

2.1 Preparing Architecture of Intelligent Tutoring System

Creating distinct modules for the architecture of an Intelligent Tutoring System holds paramount importance (6). The schematic representation of Modules for ITS adapted is shown in Fig. 1. A group comprising 30 postgraduate students specializing in regulatory affairs was selected for the study.

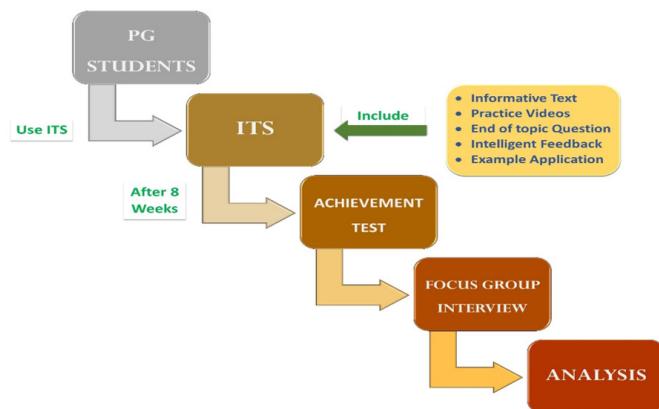


Fig. 1 Schematic flow of ITS Tool

2.2 Student prior knowledge to learn the topic of a subject

The selected topic for instruction was the drug product life cycle. Before delving into the specifics of this topic, an Initial Teaching System (ITS) tool was utilized to present a conceptual map (Fig. 1). This map was designed to assess students' prior knowledge regarding the product life cycle, serving as an evaluative measure to gauge their understanding of the terminology and processes depicted within the map (7). This approach allowed the educator to ascertain the students' foundational grasp of essential concepts before proceeding with the instructional content.

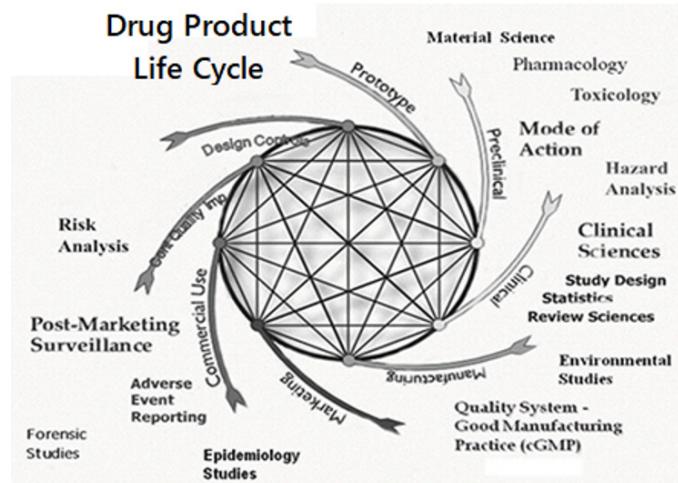


Fig. 2 Sample Concept Map of Topic

2.3 Prototyping of Tutorial

In response to student feedback, the students were categorized into two groups: slow learners and fast learners, based on their background preparation related to the selected topic. Subsequently, a supplementary tutorial was developed within the ITS tool, structured as a content repository (refer to Fig. 3). The tutorial content was organized into two modules: the student knowledge module and the expert knowledge module (8). Both tutorial modules included informative text, video links, end-topic questions, practical applications, and other relevant resources. The modules were created using Learning Management System (LMS) software, such as Classplus, Graphy, Kahoot, etc (9). All students were granted access to the prepared ITS tool tutorial on the selected topic for a minimum duration of eight weeks.

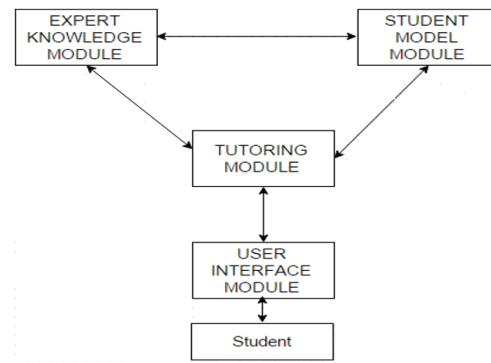


Fig. 3. Architecture of content repository for ITS System

2.4 Feedback questionnaire

Following the 8-week tutorial phase of the ITS tutoring system, students were provided with a questionnaire to gather feedback regarding the designed ITS process achievement (9). The questionnaire was structured around three key areas about the ITS tutorial system: usefulness, ease of use, and behavioral intention to use the tool, as illustrated in Table 1.

Perceived Usefulness	Perceived Ease of Use	Behavioral Intention to Use
Time and Place Flexibility Equal Opportunity Interaction with diverse cultures Immediate feedback Multimedia Usage Increase in Motivation Active participation Supporting learning Economy Repeatability	The Ease of Learning to Use the System The Ease of Using the System The Ease of Acquiring the System Using Skills	Learning About the Developments in the Area Recommending the System to Colleagues is a Good Idea to Use the System

Table 1. Interview Questions in three areas

2.5 Collection of Data and Interview

The distributed questionnaires were collected from the students, and each student was subsequently interviewed.

3. RESULT AND DISCUSSION

Below are the sample responses from the student questionnaire for feedback during the interview process. All responses from the 30 students were collected and categorized based on commonalities:

Category 1 Said the following about the usefulness of the ITS: 'When in the classroom, seeking assistance from my professor about how to apply my knowledge, that meant I somehow had a gap in my learning. However, in this course, I found myself consistently redirected to areas where I lacked understanding. And that way, I became thoroughly prepared for the assessment test on the topic.'

Category 2 of course, there was the advantage of time and place

'I could log in anytime I wanted, and I could decide how long I would be studying. Not two straight hours like in class. Given my tendency to become easily distracted in class, this flexibility proved invaluable. I could log in and study when I couldn't sleep. So, I don't miss the important basic topics. I couldn't have learned as much in class as I did with this tutorial.'

Category 3 Elaborated on the comforting side of the ITS tutorial

'I experienced the comforting aspect of the ITS system when I logged in two days before the exam for review. Surprisingly, I found that I could recall most of the material without difficulty. I realized that I hadn't forgotten many things that I had intended to review just before the exam. This shortened my review time significantly and contributed to a sense of calmness and preparedness.'

Category 4 'I found benefits of flexibility in terms of time and location, the importance of repeatability.'

Category 5 'I achieved complete learning by ensuring I covered every topic through repetition. This process of consolidation greatly enhanced my understanding and retention. Notably, it proved advantageous in terms of scoring in assessment tests.'

Category 6 'I would have been unaware of why I answered incorrectly and which page held the correct information. It's very sensible of the system to make me repeat my "missing" pages as you cannot unlock the next pages without first learning the current page.'

Category 7 'I experience significant challenges with distraction. Initially, during class sessions, I am able to focus and absorb information for approximately the first 20 minutes. However, after this initial period, I often find myself becoming increasingly distracted and losing track of the lesson. The system is more comfortable since I can use it for shorter but more frequent periods. Although I initially felt apprehensive about utilizing this module, I have found that I am ultimately more successful and productive when using it.'

The integration of this tutorial into the ITS tool was aimed at addressing identified gaps in comprehension, providing additional support, and enhancing the learning experience for students.

The collection of student data on their prior knowledge of the topic was crucial for designing personalized learning experiences and effective instructional strategies tailored to individual students.

The modules on the selected subject topic were meticulously designed and integrated to serve as the foundational elements that collectively improved the functionality of the system. The modular approach enabled seamless customization, scalability, and simplified maintenance. Furthermore, it ensured the development of a comprehensive and well-organized framework, facilitating efficient communication between different components.

A content repository, serving as a comprehensive collection of educational materials, acted as a valuable reference point for both students and instructors.

Considering the feasibility constraints such as high cost and logistical challenges associated with the aforementioned approach, the Information Technology in Education (ITS) tool method emerged as a promising alternative. By leveraging technology, this method offered a dynamic and personalized learning experience, mitigating the limitations of traditional education and fostering more inclusive and effective teaching practices.

4. CONCLUSION

This study investigated the acceptance of ITS tools among PG Regulatory Affairs students, considering their diverse

knowledge backgrounds. Students utilized the ITS to accomodate their individual needs. Data collected from focus group interviews highlighted several key aspects of the ITS, including –

- its flexibility for use at various times and locations,
- the capacity to review material, and
- its ability to foster an effective learning environment.

The findings indicated that students found the system as easy to learn and use. This indicated, there is potential value in familiarizing teacher candidates and educators with these systems to facilitate their seamless integration of technology into teaching practices.

REFERENCES

1. Atherton, M. C. (2014). Academic Preparedness of First-Generation College Students: Different Perspectives. *Journal of College Student Development*, 55, 824-829.
2. Ilić, M., Mikić, V., Kopanja, L. et al. Intelligent techniques in e-learning: a literature review. *Artif Intell Rev* 56, 14907–14953 (2023). <https://doi.org/10.1007/s10462-023-10508-1>.
3. Ali, Zuraaina. "Artificial intelligence (AI): A review of its uses in language teaching and learning." In *IOP Conference Series: Materials Science and Engineering*, vol. 769, no. 1, p. 012043. IOP Publishing, 2020.
4. Exploring the Role of Regulatory Affairs Professionals in the Pharmaceutical Industry <https://www.aissel.com/blog/Exploring-the-Role-of-Regulatory-Affairs-Professionals-in-the-Pharmaceutical-Industry>. 4 Jan 2024
5. O., A. M., & A., A. O. (2011). NOTE FOR EDITOR: Design And Development Of An Intelligent Instructive System: (Scholastic Tutor (St*). *Turkish Online Journal of Distance Education*, 12(4), 34-44.
6. Shinky Sharma, Snehal Ghorpade, Anikit Sahni, Niti Saluja, 2014, Survey of Intelligent Tutoring Systems: A Review on the Development of Expert/Intelligent Tutoring Systems, various Teaching Strategies and Expert Tutoring System Design Suggestions, *INTERNATIONAL JOURNAL OF ENGINEERING RESEARCH & TECHNOLOGY (IJERT)* Volume 03, Issue 11 (November 2014).
7. Gurlitt, J., & Renkl, A. (2010). Prior knowledge activation: how different concept mapping tasks lead to substantial differences in cognitive processes, learning outcomes, and perceived self-efficacy. *Instructional Science*, 38(4), 417–433. <http://www.jstor.org/stable/23372857>
8. Sharma, P., Harkishan, M. Designing an intelligent tutoring system for computer programming in the Pacific. *Educ Inf Technol* 27, 6197–6209 (2022). <https://doi.org/10.1007/s10639-021-10882-9>
9. By Erin Wilson. 9 Learning Management System (LMS) Examples (These are nine noteworthy examples of LMS). Feb 14, 2022. <https://e-student.org/examples-of-lms/>